

REMARKS

The foregoing amendments and the following remarks are responsive to the Office Action dated April 21, 2008 ("Office Action"). Claims 1-2, 5-16, and 25-31 remain pending in the present application.

Applicants respectfully traverse the present rejection. However, to expedite the prosecution of the present application, Applicants have amended Claim 1 to further clarify distinctions between the invention set forth in Claim 1 and the cited references. Applicants respectfully request the Examiner to reconsider and allow all of the above-listed claims in view of the foregoing amendments and the following comments, and expressly reserve the right to further prosecute the original version of any claims through continuation practice or otherwise.

Claims 1, 5, 7-9, 12-15, 26-29, and 31 are not anticipated by Reed under 35 U.S.C. 102(b)

The Examiner rejected Claims 1, 5, 7-9, 12-15, 26-29, and 31 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,827,530 ("Reed"). Respectfully stated, Claims 1, 5, 7-9, 12-15, 26-29, and 31 are not anticipated by Reed.

Claims 1 and 28:

Claim 1 has been amended to further define and particularly point out the scope and meaning of one or more of the limitations set forth in Claim 1. Without limitation, amended Claim 1 is directed to a fluid medication delivery device comprising, inter alia (underlining added):

- a fluid impermeable layer, a fluid semi-permeable layer, a fluid reservoir, the semi-permeable layer and the impermeable layer having a continuous seal therebetween to define a periphery of the fluid reservoir;
- at least one internal wall within the periphery of the fluid reservoir configured so as to form multiple interconnected regions within the fluid reservoir, the internal wall formed by securing a portion of the fluid impermeable layer located inside the periphery to a portion of the fluid semi-permeable layer located inside the periphery such that a portion of the fluid impermeable layer abuts a portion of the fluid semi-permeable layer;

- a fluid inlet communicating with the fluid reservoir, the fluid inlet comprising a valve configured to permit fluid entry into the fluid reservoir, the fluid inlet adapted to permit the delivery device to be selectively connectable to a connector for a supply of fluid, the delivery device adapted to selectively secure the connector in the radial and axial direction, wherein the valve comprises a one-way valve configured to permit fluid to enter the fluid reservoir and to prevent fluid from exiting the fluid reservoir through the fluid inlet.

Similarly, Claim 28 has been amended to further define and particularly point out the scope and meaning of one or more of the limitations set forth in Claim 28. Without limitation, amended Claim 28 is directed to a fluid medication delivery device comprising, inter alia (underlining added):

- a fluid impermeable layer, a fluid semi-permeable layer, a fluid reservoir, the semi-permeable layer and the impermeable layer having a continuous seal therebetween to define a periphery of the fluid reservoir;
- at least one internal seam inside the periphery of the fluid reservoir configured to segment of fluid reservoir into multiple interconnected regions, the seam formed by securing a portion of the fluid impermeable layer located inside the periphery to a portion of the fluid semi-permeable layer located inside the periphery such that a portion of the fluid impermeable layer abuts a portion of the fluid semi-permeable layer;
- a fluid inlet communicating with a fluid reservoir, said fluid inlet comprising a valve configured to permit fluid entry into the fluid reservoir, the fluid inlet adapted to permit the delivery device to be selectively connectable to a connector for a supply of fluid.

In particular, Reed does not disclose or suggest at least one internal wall or seam within the periphery of the fluid reservoir wherein the at least one internal wall/seam is formed by securing a portion of the fluid impermeable layer located inside the periphery to a portion of the fluid semi-permeable layer located inside the periphery such that the portions of the layers abut one another.

Feature 52 of Reed's fillable patch is not an internal wall or seam located within the periphery of the fluid reservoir but, rather identifies the perimeter of Reed's fillable patch. Thus, while feature 52 of Reed's fillable patch may bear similarity to the continuous seal between the semi-permeable layer and the impermeable layer defining the periphery of the fluid reservoir, Applicants submit that feature 52 of Reed's fillable patch does not anticipate Applicant's internal wall or seam as defined in Claims 1, 28, respectively.

Additionally, Applicant's fluid inlet set forth in Claim 1 has, inter alia, a valve comprising a one-way valve configured to permit fluid to enter the fluid reservoir and configured to prevent fluid from exiting the fluid reservoir through the fluid inlet. Additionally, Applicant's fluid inlet set forth in Claim 28 is adapted to permit the delivery device to be selectively connectable to a connector for a supply of fluid and has, inter alia, a valve configured to permit fluid entry into the fluid reservoir. Respectfully stated, Reed does not disclose or suggest such a valve or one-way valve at column 5, lines 1-15, as is stated in the Office Action. Contrary to the Examiner's conclusions, Reed does not disclose or suggest any form of a valve formed on the topical delivery device 11. In particular, at column 5, lines 1-15, Reed discloses that "the backing layer [42] is pierced via puckered wrinkle 46 through puncture hole 49" with the needle 48 of a syringe 50 (underlining added). In this arrangement, Applicants submit that Reed's needle 48 penetrates directly through the backing layer 42 and not through a valve.

Additionally, Reed does not disclose a fluid inlet adapted to secure a connector in the axial direction, as is set forth in Claim 1. Reed does not disclose or suggest any features on the embodiments of the delivery devices disclosed therein that can secure the needle 48 of the syringe 50 in the axial direction.

Finally, Reed does not disclose or suggest the one-way valve of Claim 1 which is configured such that, when the connector is secured to the fluid inlet, the one-way valve permits fluid to enter the fluid reservoir and prevents fluid from exiting the fluid reservoir through the fluid inlet. In Reed, when the needle 48 of the syringe 50 has penetrated through the backing layer 42, Reed does not disclose or suggest that the topical delivery device 11 is configured to prevent fluid from exiting the reservoir 56. In other words, Reed does not disclose or suggest any feature that would prevent fluid from exiting the reservoir using the syringe 50 (i.e., when the

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plunger of the syringe 50 is withdrawn so as to draw fluid into the syringe 50, which is a typical function or capability of the syringe 50 depicted by Reed.

For the above-stated reasons, Applicants submit that Reed fails to disclose each and every element recited by amended Claims 1 and 28. Accordingly, Applicants respectfully request the Examiner to withdraw the rejection of Claims 1 and 28 to pass these claims to allowance.

Claim 7:

Regarding Claim 7, in contrast with Reed, Claim 7 is directed to a fluid medication delivery device comprising (among other things) a fluid impermeable pouch having at least two limitations that are not disclosed or suggested by Reed. First, the fluid impermeable pouch of Claim 7 has a second wall opposing a first wall. While Reed may disclose or suggest a first wall and a fluid semi-permeable layer, which Applicants do not concede, Applicants submit that Reed does not disclose or suggest the second wall set forth in Claim 7, and the Office Action fails to accurately point to any disclosure or suggestion in Reed that relates to the second wall. Note that Reed's feature 16 is described as a diffusion membrane (*see* column 3, line 44), feature 12 is an adhesive layer (*see* column 3, lines 39-40), feature 18 identifies the perimeter of Reed's delivery device 10 and, therefore, not a wall or layer (*see* column 3, line 48), and feature 22 is described as a backing layer (*see* column 3, lines 53).

Therefore, Applicants submit that Reed's delivery device 10 is described to have only the following layers (notwithstanding the removable release liner 14) and Applicants submit that a layer or feature that anticipates the second wall set forth in Claim 7 is absent from Reed.

- 1) a backing layer 22 (which the Office Action compares to the first wall in Claim 7),
- 2) a diffusion membrane 16 (which the Office Action compares to the fluid semi-permeable layer in Claim 7), and
- 3) an adhesive layer 12 (which the Office Action does not compare to any features in Claim 7).

Further, as set forth in Claim 7, the second wall of the fluid impermeable pouch has a plurality of openings. Applicants submit that Reed does not disclose or suggest such a plurality of openings in any of its layers, and the Office Action fails to point out any disclosure or suggestion in Reed that relates to such limitation.

Finally, without limitation, Claim 7 also states that the semi-permeable layer covers the diffusion area of the delivery device and that the semi-permeable layer is configured such that fluid within the fluid reservoir must pass through the semi-permeable layer before exiting the delivery device. This limitation is also absent in Reed.

Claims 5, 8-9, 12-15, 26-27, and 29:

Regarding Claims 5, 8-9, 12-15, 26-27, and 29, respectfully stated, these claims are not anticipated or suggested by Reed for at least the same reasons as for the claim or claims from which they depend, and also because they each recite further patentable distinctions. For example, the syringe 50 disclosed in Reed does not “allow the continuous delivery of fluid to the fluid medication delivery device,” as is set forth in Claim 27. As is known in the art and underscored by the illustration in Figure 4, Reed’s syringe 50 allows only a limited or discrete amount of fluid to be delivered to Reed's fillable patch.

Accordingly, Applicants respectfully request the Examiner to reconsider and withdraw the rejection of Claims 1, 5, 7-9, 12-15, 26-29, and 31 in view of the amendments and clarifications listed above, and to pass these claims to allowance.

Claims 2, 6, 10-11, and 16 are not unpatentable over Reed in view of Deniega under 35 U.S.C. 103(a)

The Office Action rejects Claims 2, 6, 10-11, and 16 under 35 U.S.C. 103(a) as being unpatentable over Reed in view of U.S. Patent No. 6,350,253 (“Deniega”). Applicants submit that Claims 2, 6, 10-11, and 16 define patentable distinctions over the cited references, not only because they depend from allowable Claims 1 and 7, but also on their own merit. Respectfully stated, Deniega fails to rectify the failure of Reed to disclose, among other elements, the elements listed in amended Claims 1 and 7, as set forth in more detail above. Accordingly, Applicants respectfully request that the Examiner withdraw the rejection of Claims 2, 6, 10-11, and 16, and pass these claims to allowance.

Claims 25 and 30 are not unpatentable over Reed in view of Weston under 35 U.S.C. 103(a)

The Office Action rejects Claims 25 and 30 under 35 U.S.C. 103(a) as being unpatentable over Reed in view of U.S. Patent No. 4,605,309 (“Weston”). Applicants submit that Claims 25

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and 30 define patentable distinctions over the cited references, not only because they depend from allowable Claims 1 and 28, respectively, but also on their own merit. Respectfully stated, Weston fails to rectify the failure of Reed to disclose, among other elements, the elements listed in amended Claims 1 and 28, as set forth in more detail above. Accordingly, Applicants respectfully request the Examiner to withdraw the rejection of Claims 25 and 30, and to pass these claims to allowance.

No Disclaimers or Disavowals

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, the Applicants are not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. The Applicants reserve the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that the Applicants have made any disclaimers or disavowals of any subject matter supported by the present application.

Co-Pending Applications of Assignee

Applicant wishes to draw the Examiner's attention to the following co-pending applications of the present application's assignee.

Serial Number	Title	Filed
10/942,735 IFLOW.149CP1	FLUID MEDICATION DELIVERY DEVICE	09-16-2004

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Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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